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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,677	02/05/2001	Jan Otto Solem	SOLEM3A	3473

7590 08/28/2002

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Washington, DC 20001

EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 08/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/775,677

Applicant(s)

SOLEM ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 21-40, 73 and 74 is/are pending in the application.
- 4a) Of the above claim(s) 1-13, 24-27, 29, 31-36, 73 and 74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 15 and 17 is/are allowed.
- 6) ☒ Claim(s) 16, 21, 23, 28 and 37-40 is/are rejected.
- 7) ☒ Claim(s) 14, 22 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-17, 21-40, 73 and 74 in Paper No. 9 is acknowledged.
2. Applicant's election with traverse of Species 9 (Figures 19-20), claims 14-17, 21-23, 28, 30 and 37-40 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that it would not constitute a serious burden to examine plural species. This is not found persuasive because the species restriction is made based on the patentable distinctness of the different embodiments clearly shown in the Figures.

The requirement is still deemed proper and is therefore made FINAL.

Response to Amendment

3. The amendment filed 8/6/02 has been entered as Paper No. 9. Claims 18-20 and 41-72 have been canceled. Currently, the pending claims are 1-17, 21-40, 73 and 74, and the claims being considered for examination on the merits are 14-17, 21-23, 28, 30 and 37-40.

Interference

4. Claims 22 and 53 of this application are asserted by applicant to correspond to claim(s) of U.S. Application No. 09/494,233, now U.S. Patent No. 6,402,781, and U.S. Application No. 09/909,193, which is not published. Claim 53 of this application has been canceled, and therefore, the request for interference based on this claim is moot.

X 5. The examiner does not consider this claim 22 to be directed to the same invention as that of U.S. Patent No. 6,402,781 because the claimed invention of the '781 patent requires a forming element attached to the elongate body for manipulating the elongate body from the first transluminal configuration to the second remodeling configuration, and a lock for retaining the elongate body in the second configuration at least in part within the coronary sinus. See claim 1. Claim 15 of the '781 patent requires a forming element attached to the elongate body, wherein the forming element is adapted to be severed. The current application claims neither the forming element nor the lock. Furthermore, the concepts of a lock and forming element adapted to be severed are not even disclosed in the specification. Accordingly, an interference cannot be initiated based upon this claim.

Specification

✓ 6. It is unclear if "Duran", "Carpentier" and "Cosgrove-Edwards", as mentioned on page 4, lines 4, 7 and 8, respectively, are trademarks. If they are, they have been noted in this application. They should be **capitalized** wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

7. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the

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✓ following is required: claim 14 requires that the elongate body comprise at least one stent section *at a distance* from each end of the elongate body. The elected embodiment shown in Figures 19 and 20 clearly shows that the stent sections are *at* each end of the elongate body, and not at a distance from each of them. Claim 19 also requires that the at least one stent section at each end reduces in length when expanded to shorten and bend the elongate body. This is in conflict with page 9, lines 22-24 of the specification, which states that the proximal and distal stent sections "should be expandable without substantial length reduction".

Claim Objections

8. Claims 14 and 30 are objected to because of the following informalities:

- ✓ a. Claim 14, line 13, --at least one-- should be inserted after "said".
- ✓ b. Claim 30, line 3, --in part-- should be inserted after "least".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 23 and 28 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 23 requires that the elongate body is adapted to be

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permanently implanted in the patient, and claim 28 requires that the length between proximal and distal ends of the elongate body be less than about 10cm. These limitations are not supported by the specification.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16 and 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 16 is indefinite because it is not commensurate with the scope of claim 14, on which it depends. Claim 14 requires that the at least one stent section located at distal and proximal ends of the elongate body reduce in length when expanded to shorten and bend the elongate body. Claim 16 then requires that the distal and proximal stent sections are expandable without substantial length reduction. The conflict in limitations must be resolved.

13. Claim 37 recites the limitations "the adjacent tissue structure" and "the body space" in lines 2 and 5, respectively. There is insufficient antecedent basis for these limitations in the claim. Examiner suggests changing "the body space" to --the vessel-- so that the claim terminology is commensurate with that of claim 21, on which it depends.

14. Claim 37 is indefinite because "its diameter" on line 6 lacks antecedent basis in the claim because the space has a diameter, not the adjacent tissue. Examiner suggests changing "its diameter" to --the diameter of said space--.

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15. Claims 38 and 39 are indefinite because it is unclear how they further limit the claimed invention of a medical device for remodeling an extravascular tissue structure adjacent to a vessel in a patient. The deployment system is not a structural element of the medical device itself. These claims should be canceled.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

17. Claims 21, 37 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Jayaraman (USPN 5,713,949).

Jayaraman discloses a stent with all the structural elements of claim 21. See Figure 21 for elongate body (70) extending between a proximal and distal end, and that is adjustable between a first configuration having a first shape such that the elongate body is adapted to be delivered at least in part into the vessel (Figure 22), and a second configuration having a second shape such that the elongate body is adapted to exert a force from within the vessel onto the extravascular tissue (Figure 24). When the stent is expanded, it is clear from Figure 24 that the vessel lumen is increased such that the diameter is larger than the diameter of the lumen

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proximal and distal to the stent. This increased diameter will inherently exert a force onto the surrounding tissue, and this force will be capable of remodeling the surrounding tissue.

Claim 37 does not provide any structural limitations to the claimed invention of the medical device, but rather recites only functional language. The elongate body, having all the structural elements of claim 21, is certainly capable of reducing the diameter of space circumscribed by an adjacent tissue structure wall if it is placed in an appropriate vessel.

With respect to claim 40, see rejections to claims 21 and 37, supra, wherein the vessel provides as the body space.

Allowable Subject Matter

18. Claims 14, 15 and 17 are allowed.

19. Claims 22 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

20. Claims 16, 38 and 39 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

21. Claims 23 and 28 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.

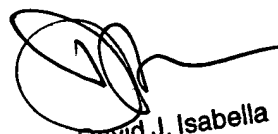


Urmi Chattopadhyay

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August 23, 2002



David J. Isabella
Primary Examiner